REMARKS

Remark 1:

Applicant has amended Claims 1 and 7-11. Applicant submits that the prior art does not teach stimulation of collagen biosynthesis without thermal damage to the epidermis in conjunction with applying a wound healing composition to the skin to achieve improved cotlagenesis in the skin.

Remark 2:

Applicant requests Examiner withdraw O'Donnell as an anticipating reference. Applicant points out that O'Donnell teaches the use of anti-inflammatories, anti-oxidants and neo-collagen promoters that are to be used post operatively to the laser treatment for 30 to 90 days. This is described in column 6 lines 46-50. He does not teach the mechanism of interaction of these drugs with the laser and makes no suggestion that the use of these drugs with the laser is any better than if they were used separately. Since the teaching groups a broad range of well-known skin care pharmaceuticals together that all have different mechanisms of interaction, it implies that there may not be any laser drug interaction benefit.

Remark 3:

In contrast, the present invention describes precisely how the wound healing compounds work to enhance collagen production. In particular, Applicant claims that the drugs must be used in conjunction with a laser to be most effective. There is a multiplying factor that makes the combination use more effective than the use of the laser or drug separately. Use of a drug post operatively as taught by O'Donnell would not work as well and is not included within the scope of the present invention.

Remark 4:

A key mechanism is that the laser thermally injures the sub-surface tissue causing the body to

generate its own wound healing response. During the time that the body is being stimulated to generate new collagen, the drug application in conjunction with the laser will enhance this wound healing response that generates new collagen. This critical time has been shown to be within a few hours of laser application and while the surface of the skin exhibits minor erythema. The drug can also be administered immediately pre-operatively to prepare the body for the laser thermal injury and stimulation. In a preferred embodiment of the present invention, both the drug delivery and laser energy need to overlap or be in conjunction to be effective.

Remark 5:

It is not obvious from the prior art that the mechanism of laser stimulation of collagen and the mechanism of drug wound healing enhancement may be multiplied and enhanced when the two methods are used in conjunction. O'Donnell does not teach this. Prior art that may describe the use of a wound healing drug alone to enhance collagen production does not mention that the effect may be multiplied and enhanced by the application of laser energy to stimulate the body's wound healing response. It is not obvious to one skilled in the art that a laser may be used in this novel and unique manner.

Remark 6:

Applicant requests Examiner withdraw Purchio as an anticipating reference. Applicant also points out that Purchio does not anticipate the present invention. Purchio teaches the use of chemotherapy and radiation treatment to increase the treatment efficiency. The radiation that Purchio describes is ionizing or particle radiation that has energy levels so high that tissue is destroyed on a molecular level and may become radioactive. This radiation is generated in a hospital synchrotron or from the nuclear decay of a radioactive particle such as radium or plutonium. This is a completely different mechanism with different equipment than is taught in the present invention. The present invention teaches the use of much lower energy electromagnetic waves in the visible or broadcast radio range that will only heat tissue, not disrupt

it. Purchio does not describe the method of wound healing response. The goal of Purchio's radioactive treatment is to completely destroy tissue, not stimulate or enhance it.

Remark 7:

Applicant requests Examiner withdraw Hale as an anticipating reference. Hale teaches the use of electro-magnetic energy (EM) to the skin to enhance the effects of a wound healing composition. Hale does not teach a method to enhance the biological reaction in the skin, only that the drug is delivered to site easier. Hale does not utilize electro-magnetic energy to drive ions into the skin. Hale teaches the use of a static electric DC field only. An EM field is an alternating wave that radiates through free space with both positive and negative polarity swings. Radiowaves and lasers are examples of EM waves. EM waves do not drive ions across membranes as described by Hale. They only cause ions to vibrate in place causing heat, not movement. In contrast, a static DC electric field as described by Hale will provide a force onto an ion and enable it to move across a membrane surface. EM radiation cannot possibly work to deliver drugs using the Hale invention. Nowhere does Hale mention EM radiation such as microwaves or lasers in his invention. Hale does not even mention EM radiation anywhere, only DC electric fields. Hale does describe the use of direct current between two electrodes on the skin to generate about 1 milliamp of current into the skin, which transports the ionic drug along with it. This current can be generated with two wires hooked into a 9-volt battery. In contrast, an alternating electro-magnetic wave as used in the present invention such as a laser or microwave requires a complex oscillator generator and an antenna or lens to allow the wave to propagate through space prior to hitting the skin. The mechanisms of the present invention and Hale are completely different. The method of the present invention is not obvious to one trained in the art and using Hale. The present invention is not claiming enhanced penetration of the drug as Hale describes. The present invention is not claiming that the laser energy acts directly on the drug. The present invention only claims that once the drug is present the effect is enhanced by a thermal injury caused by the laser.

CONCLUSION

Applicant respectfully submits that for all the foregoing reasons, the claimed subject matter describes patentable invention. Furthermore, Applicant submits that the specification is adequate and that the claims are now in a condition for allowance. No new matter has been entered.

Applicant hereby respectfully requests Examiner to withdraw the cited references as anticipating or obviating prior art, enter these amendments, find them descriptive of useful, novel and non-obvious subject matter, and authorize the issuance of a utility patent for the truly meritorious, deserving invention disclosed and claimed herein.

Without further, Applicant does not intend to waive any claims, arguments or defenses that they may have in response to any official or informal communication, paper, office action, or otherwise, and they expressly reserve the right to assert any traverse, additional grounds establishing specificity and clarity, enablement, novelty, uniqueness, non-obviousness, or other patentability, etc.

Further, nothing herein shall be construed as establishing the basis for any prosecution history or file wrapper estoppel, or similar in order to limit or bar any claim of infringement of the invention, either directly or under the Doctrine of Equivalents.

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Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this paper and the documents attached hereto are being deposited in a postage prepaid, sealed envelope with the United States Postal Service using First Class Mail service under 37 CFR 1.08 on the date indicated and is addressed to "Commissioner for Patents, Virginia 22313-1450". Signed: _____.
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